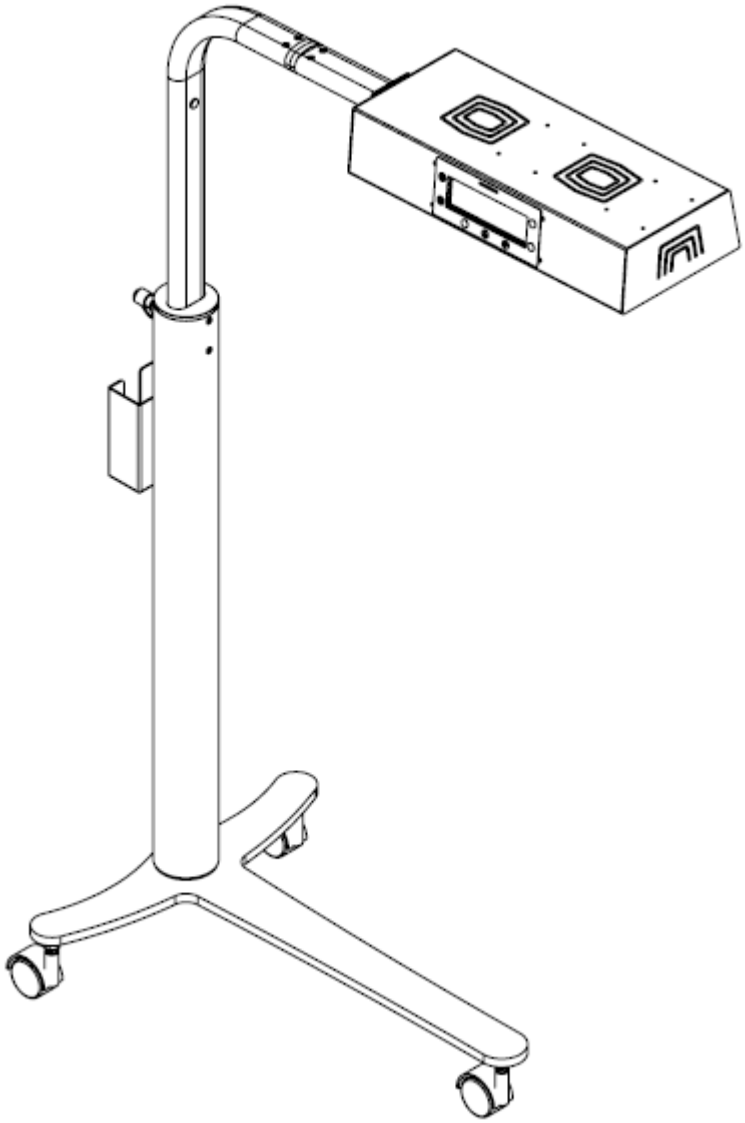
Bililed® Maxi

Intensive LED Phototherapy Unit

User's Manual

(Rev 4))(12.09.2012)



NOTICE

Proprietary Information:

This document contains information in which NOVOS, claimed proprietary rights. The information may not be reproduced in whole or in part except as authorized in writing by NOVOS. This information is the property of NOVOS, it is provided solely for use intended.

Repairs/Modifications:

Repairs on this device shall be performed only by NOVOS or Factory Authorized Service Centers. Information about repairs can be obtained from NOVOS or Authorized Dealers. NOVOS will not be responsible for injury to persons or damage to property arising directly or indirectly out of unauthorized repairs or modifications to this device. Furthermore, any unauthorized repairs or modifications void any warranty extended by NOVOS.

This document is provided for your information only. It will not be exchanged or updated without request.

Definitions

WARNING: Warnings are directions which, if they are not followed, can cause fatal or serious injuries to a user, engineer, patient or any other person or can lead to a mistreatment.

CAUTION: Cautions are directions which, if they are not followed, can cause damage to the system described in this manual.

Trademarks:

NOVOS name and logo are registered trademarks of NOVOS Tıbbi Cihazlar San. Tic. Ith.ve Ihr.Ltd.Sti.

Bililed ® is registered trademark of NOVOS Tıbbi Cihazlar San. Tic. Ith.ve Ihr. Ltd.Şti.

Table of Contents

Important Safety Information 3
Intended Use 11
Parts and Control Systems of Equipment 13
Checking Readiness for Operation 20
Equipment Operation 22
Safety Systems& Alarms 28
Routine Cleaning and Maintenance 30
Troubleshooting 33
Technical Characteristics 35

Important Safety Information

Important Safety Information 4
Symbols 4
Operator's Responsibility for Patient Safety 5
Limitation of Liability 5
Warranty 6
Warnings 7
Warnings and Cautions for Using of Equipment 7
Warnings Related with Possible Physiological Affects 9
Warnings Related with Ambient Conditions 10

IMPORTANT SAFETY INFORMATION

Symbols Used

Symbol	Meaning
	Attention : Check Manual
	Type BF Equipment
	Attention : Risk of Electric Shock
	Patient Eye Protector
I	ON (Electric power being supplied)
0	OFF (No power being supplied)
	For using please see auxiliary documents

Operator's Responsibility for Patient Safety

Attention

Operating the device without a complete and thorough understanding of its attributes is unsafe and may cause harm to the patient. It is important that this part of manual be read and understood in its entirety before operating the device. PLEASE READ IT CAREFULLY!

This equipment should be used for the purpose specified under " Intended Use".

Observe all warnings and cautions rendered throughout this manual and labels on the equipment.

The design of this equipment, the accompanying literature, and the labeling on the equipment take into consideration that the purchase and use of this equipment are restricted to trained professionals, and that certain inherent characteristics of the equipment are known by trained operator.

Instructions, warnings, and caution statements are limited, therefore, largely to the specifics of the NOVOS design. This publication excludes references to various hazards which are obvious to a medical professional and operator of this equipment, to the consequences of product misuse, and to potentially adverse effects in patients with abnormal conditions. Product modification or misuse can be dangerous. NOVOS disclaims all liability for the consequences of product alterations or modifications, as well as for the consequences which might result from the combination of this product with other products whether supplied by NOVOS or by other manufacturers if such a combination is not endorsed by NOVOS.

Patient monitoring

The operators of this phototherapy system must recognize their responsibility for choosing appropriate safety monitoring that supplies adequate information on equipment performance and patient condition. Patient safety may be achieved through a wide variety of different means ranging from electronic surveillance of equipment performance and patient condition to simple, direct observation of clinical signs. Responsibility for the selection of the best level of patient monitoring lies solely with the equipment operator.

Limitation of Liability

NOVOS liability, whether arising from or related to manufacture and sale of goods, their installation, demonstration, sales representation, use, performance, or otherwise, including and liability based upon NOVOS 's product warranty or any other cause of action whatsoever, regardless of any fault attributable to NOVOS and regardless of the form of action (including, without limitation, breach of warranty, negligence, strict liability, or otherwise).

NOVOS shall not be liable for, nor shall buyer be entitled to recover any special incidental or consequential damages or for any liability incurred by buyer to any third party in any way arising from or relating to the goods.

Warranty

All NOVOS products are guaranteed to be free of defects for a period of one year from date of delivery.

Attention:
Operating the device without a complete and thorough understanding of its attributes is unsafe and may cause harm to the patient. It is important that this part of manual be read and understood in its entirety before operating the device.PLEASE READ IT CAREFULLY!

The following are exceptions of this warranty:

1. The defect shall be a result of workmanship or material. Defects caused by misuse, mishandling, tampering, or by modifications not authorized by NOVOS or its representatives are not covered.

2. Rubber and plastic components and materials are warranted to be free of defects at time of delivery. Any product which proves to be defective in workmanship or material will be replaced, credited, or repaired with NOVOS holding the option. NOVOS is not responsible for deterioration, wear, or abuse. In any case, NOVOS will not be liable beyond the original selling price.

Application of this warranty is subject to the following conditions :

1. NOVOS or its authorized representative must be promptly notified, in writing, upon detection of the defective material or equipment.

2. Defective material or equipment must be returned, shipping prepaid, to NOVOS or its factory authorized service center.

3. Examination by NOVOS or its factory authorized service center must confirm that the defect is covered by the terms of this warranty.

4. Notification in writing, of defective material or equipment must be received by NOVOS or its factory authorized service center no later than two (2) weeks following expiration of this warranty.

The above is the sole warranty provided by NOVOS.

No other warranty expressed or implied is intended. Representatives of NOVOS are not authorized to modify the terms of this warranty.

WARNINGS

WARNING

This User Manual contains extremely important information to insure the safety and the physical integrity of the patient, of the user and of the equipment. Therefore read it CAREFULLY!

Warnings for Using the Equipment

WARNING

Operating the device without a complete and thorough understanding of its attributes is unsafe and may cause harm to the patient. BILILED MAXI® should only be used by properly trained personnel under the supervision of qualified medical personnel familiar with the currently known risks and benefits of using a phototherapy device.

WARNING

Power cable plug shall be connected to mains connection permanently fixed in wall or bench, as per rule for low power electrical instillations. Never use extension cord.

WARNING

NOVOS™ BILILED MAXI™ phototherapy should be used in accordance with the ideal environmental comfort standards for a nursery that is between 23-27 ºC.

WARNING

We recommend the use of Radiation Monitor to confirm a proper lamp radiation condition to ensure a minimum radiation of 3,5 mW/cm2. The internationally acceptable level for proper treatment is 3,5 mW/cm2 (minimum value according to Mims.)

WARNING

In order to avoid eye damage of patient, use eye protector. The newborn needs eye protection.

WARNING

This device is to be used only in rooms with line power installations complying with national safety standards for hospital patient rooms (e.g., IEC/EN 601.1 “Safety of Medical Equipment” 110V or 220 V+-10% and 50-60Hz-100VA).
To maintain grounding integrity, connect only to a “hospital grade” receptacle.

WARNING

If a proper grounding system is not available, the equipment should not be used. Do not use extension cord or multiple plugs.

WARNING

Infant temperature must be monitored with particular care during phototherapy. Absorption of light through the infant’s skin will supply heat to the patient which may increase central temperature.

WARNING

Thermotherapy sets (Heated Cribs, Heated Mattresses, and Radiation Heaters) coupled to BILILED MAXI™ may rise the patient ’s body temperature to dangerous levels, so the temperature should be constantly checked by using a clinical thermometer.

WARNING

NOVOS cannot warrant or endorse the safe performance of third party accessories for use with BILILED MAXI™ phototherapy.
Only use original NOVOS accessories and parts with BILILED MAXI™ phototherapy.

WARNING

Do not use the BILILED MAXI™ in the presence of flammable anesthetics, combustible gases or cleaning substances that may cause combustion.

CAUTION

Do not push buttons with sharp, boring material or fingernail.

WARNING

Only use NOVOS original parts and accessories. Serious harm to the patient and device may result from the use of unauthorized parts or accessories.

CAUTION

Maintenance, Repair

The equipment must be inspected and serviced at regular 1 year intervals. A record must be kept on this preventive maintenance. We recommend obtaining a service contract with NOVOS through your vendor.
For repairs of BILILED MAXI™ we recommend that you contact NOVOS

WARNING

Never cover phototherapy unit with cloths, blanket, aluminum foil or other materials with the intention to boost the phototherapeutic effect. It may cause to temperature rising and/or obstruct to irradiance of light.

WARNING

Normally the original NOVOS lamps life expectance is about 20.000 hours, however it is recommended to follow up the irradiance constantly with a radiometer in accordance with the usual maintenance procedures, to assure a better evaluation of the actual efficacy of the leds. The irradiance source should be replaced always when it reaches a loss of 25% of the total irradiance for bilirubin-Ebi.

CAUTION

Before delivery, the equipment must be switched OFF.

WARNING

Mobile telephones must not be used within 10 meters (33 feet) of the phototherapy unit. Mobile phones can interfere with the function of electro medical equipment and therefore endanger the patient!

WARNING

Do not cover air circulation ports of BILILED MAXI by blanket or towel or any fabric. It may cause to temperature rising and it may affect patient skin temperature.

WARNING

Verify that power cord is connected properly to the device and all necessary measurements are supplied against disconnection.

WARNING

Only use NOVOS original LEDS. Using unauthorized LEDS may affect intensity and temperature levels defined for device.

WARNING

We recommend that the distance between patient and BILILED MAXI should be more than 30 cm.

WARNING

Use caution when moving the BILILED MAXI over uneven surfaces, e.g. rough pavement outside the hospital or into elevator, as castors may become damaged or dislodged.

WARNING

In order to avoid risk of electric shock, always disconnect power supply before starting any maintenance procedures.

WARNING

Inspect the parts of equipment and ensure it has not physical damage.
Never operate BILILED MAXI if it has damaged part or does not seem to operate properly. Contact authorized technical service of NOVOS.

WARNING

Always disconnect power supply before cleaning and disinfecting.

WARNING

To avoid any risk of infection, clean and disinfect device and accessories before any maintenance according to established hospital procedures-this applies also when returning units or parts for repair.

WARNING

If any part of power supply is directly in contact with the baby's body, do not use BILILED MAXI! Power supply of operating unit may heat up and this overheating may cause burn of patient skin.

Warnings Related with Possible Physiological Effects

WARNING

While being transitory, some collateral effects may be observed as a result from phototherapy. Among them we would emphasize the increase in peripheral blood flow with consequent vessel dilatation, erythema and an increase in insensible water loss, eyes injury an alternation in the intestinal transit.

WARNING

The operator; doctor or nurses eyes may be affected in case of long stay around the patients.

WARNING

Patient's serum levels of bilirubin should be regularly measured.

WARNING

Newborns submitted to NOVOS™ BILILED MAXI™ as to any other type of phototherapy, will require an adequate hydric supply and eyes protection during treatment, in addition to the routine nursing and medical assistance.

WARNING

During the treatment, the photo isomers of bilirubin may cause toxic effects.

WARNING

Liquid infusions and drugs should not be stored or kept within the radiation area.

WARNING

The use of reflector sheet is not adequate, because it may cause dangerous temperatures to the patient body.

WARNING

The water balance of the patient may be altered due to the use of phototherapy.

WARNING

In newborn patients with very jaundiced skin it is common to observe, after a few hours of treatment with BILILED MAXI™, that the area submitted to light appears paler and whitish. This is due to the intense action of the light on the bilirubin pigment deposited in the skin.

WARNING

Intensive phototherapy provides a rapid reduction in serum bilirubin levels thus reducing the need for blood transfusion and reducing treatment duration.

WARNING

In case of newborn patients with risk of developing high bilirubin serum levels and patients with continuously rising bilirubin concentration in spite of the application of phototherapy, the use of BILILED MAXI™ is recommended.

WARNING

Eyes of the patient lie down near the phototherapy must be protected by using barrier or/and eye protector, etc

Warnings Related with Ambient Conditions

WARNING

Ambient conditions, such as air movement and airflow may affect the thermal balance of the patient.

WARNING

Inappropriate ambient temperature may affect the thermal balance of the patient.

INTENDED USE

INTENDED USE

BILILED MAXI™ is routinely used in treatment of neonatal hyperbilirubinemia, where the patient is submitted to an exposure of concentrated radiation in the blue spectrum of visible light during a time to be determined by the attending physician depending on the case.

During the jaundice treatment, the patient is accommodated in a heated crip or incubator, depending on his/her clinical conditions. BILILED MAXI™ has been established for the purpose of jaundice treatment in hospitals.

Functions:

- 5 levels adjustable intensity
- Therapy time info
- Lamp usage time info
- Focusing light

WARNING

BILILED MAXI® should only be used by properly trained personnel under the supervision of qualified medical personnel familiar with the currently known risks and benefits of using a phototherapy device.

WARNING

Only use NOVOS original parts and accessories. Serious harm to the patient and device may result from the use of unauthorized parts or accessories.

WARNING

Intensive phototherapy BILILED MAXI™ does not replace an incubator or/and any other heated systems.

WARNING

BILILED MAXI™ is ready for operation only when all checks have been carried out successfully.

WARNING

DANGER! Risk of explosion if used in the presence of flammable anesthetics.
This device is neither approved nor certified for use in areas where combustible or explosive gas mixtures are likely.

WARNING

This device is to be used only in rooms with line power installations complying with national safety standards for hospital patient rooms (e.g., IEC/EN 601.1 “Safety of Medical Equipment” 110V or 220 V+-10% and 50-60Hz-100W).
To maintain grounding integrity, connect only to a “hospital grade” receptacle.

WARNING

The use of this device requires continuous supervision of the infant by trained nursing personnel in order to avoid immediate corrective action in situations with a risk of patient injury.

WARNING

NOVOS medical equipment conforms to the interference immunity requirements laid down in product-specific standards or in EN 60601-1-2(IEC 60601-1-2). However, depending on the design of a mobile phone and the use situation, field strengths exceeding the values generated in the immediate vicinity of mobile phones, thereby causing interference and malfunctions.

WARNING

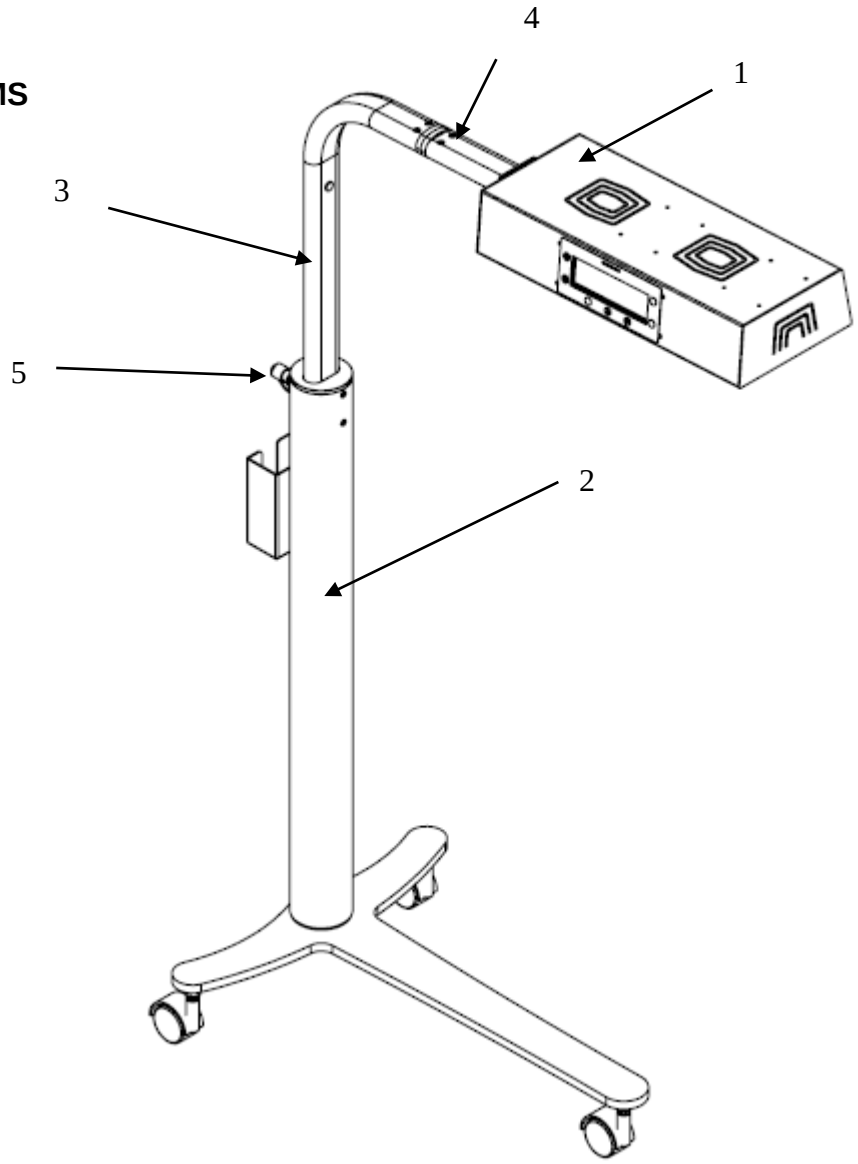
BILILED MAXI™ has not been established for using inside of incubators and it should not be exposed directly heat coming from radiant warmer. Risk of burn! Risk of explosion upon O2!

PARTS AND CONTROL SYSTEMS

Main Parts of the Equipment 14
Front View 14
Head View 15
Labels 16
Control Systems 17
Main Control Panel 17
Turn On Screen 18
Main Screen 18
Therapy Started Screen.....18
Pause Screen 18
Service Screen 18
Alarm Screen 19
Therapy Terminated Screen 19

PARTS AND CONTROL SYSTEMS

Main Parts of The Equipment



Front View

1. Head
2. Mobile Stand
3. Height Adjustable Column
4. Head rotation joint
5. Height Fixing Arm

Height Adjustable Column

Thanks to the height adjustable column It is possible to use Bililed Maxi phototherapy unit with different height of baby codes and incubators. Height of Bililed Maxi head can be adjusted approximately between100 – 150 cm.

Head Rotation Joint

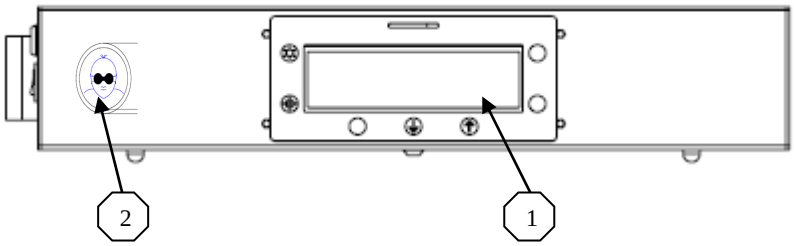
By using this joint you can position the head with an angle to side.

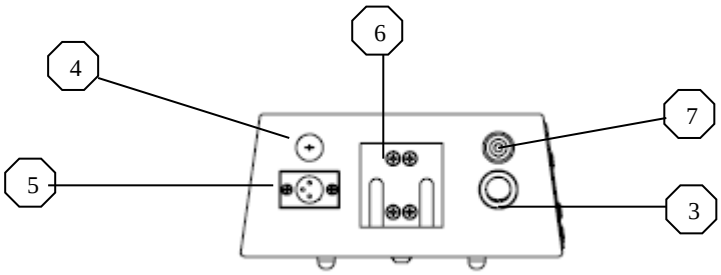
Connecting/Disconnecting the Head

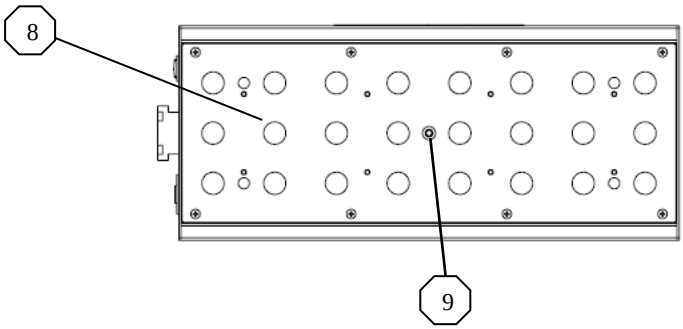
Head of Bililed Maxi can be disconnected from the mobile stand and positioned directly onto the incubator canopy. Moving the head upwards it is possibble to detach from the movement joint.

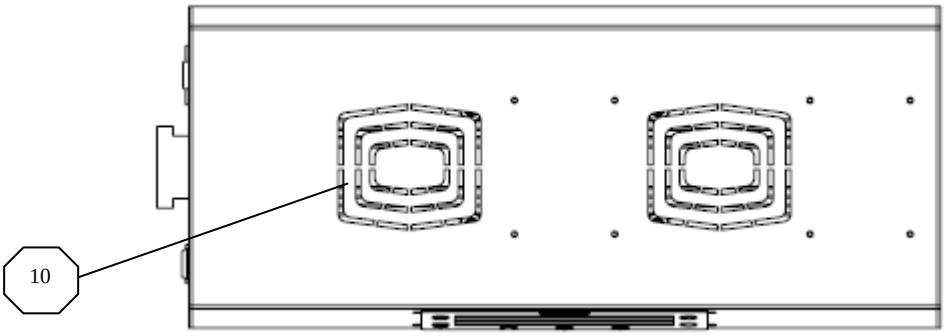
Head View

1. Control pane
2. Label of eye protector
3. On/Off Button
4. Fuse
5. Power input
6. Mounting Socket
7. Skin Temp. Probe Socket
8. Led Module
9. Focus Light
10. Cooling channel



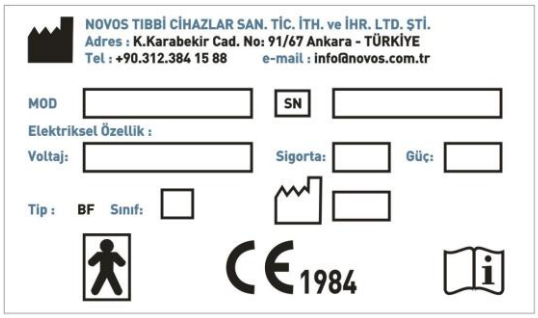






Labels

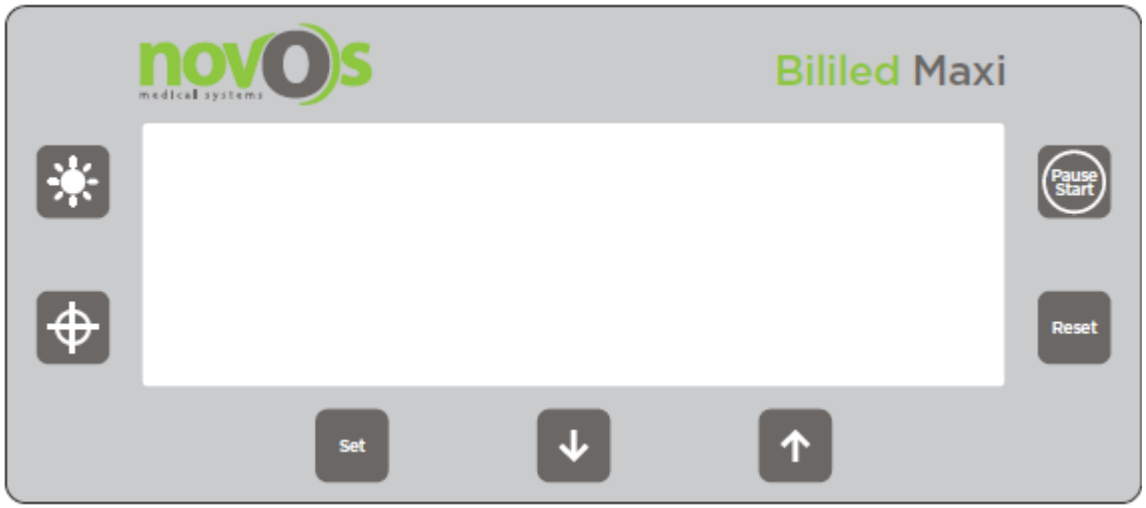
Equipment/manufacturer identification label



Warning for eye protection.

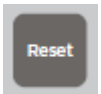
Control Systems

Main Control System



Control Panel

Therapy Start / Pause



Therapy ending

Intensity adjustment

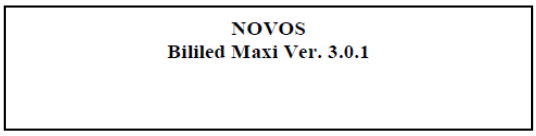
Focus /Targeting Light

Therapy Time/Skin Alarms Adjustment

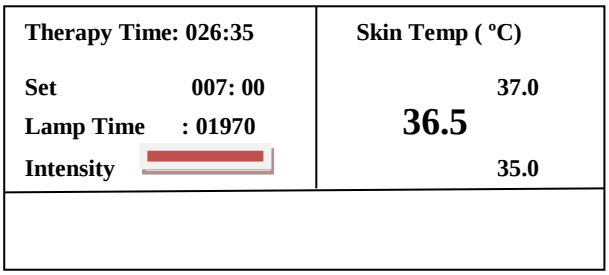
Decrease Button

Increase Button

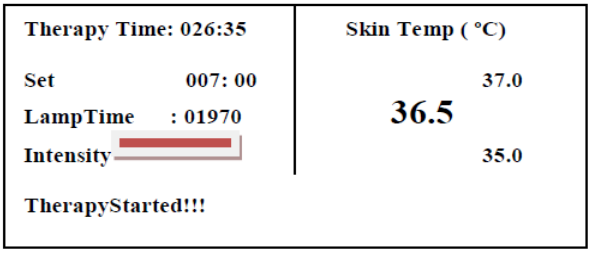
Turn On Screen



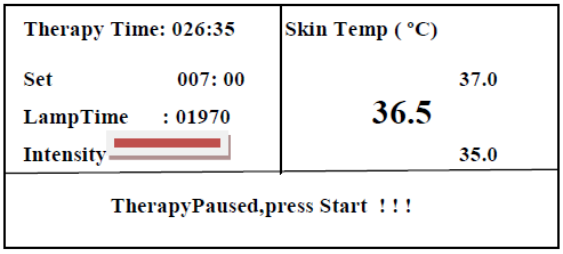
Main Screen



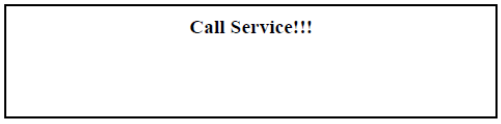
Therapy Started Screen



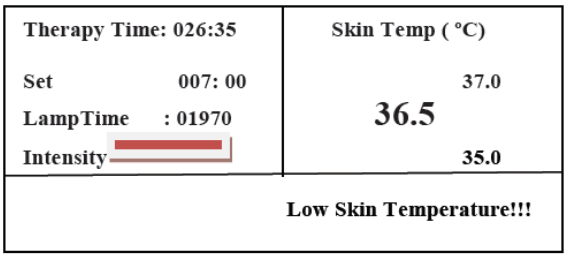
Pause Screen



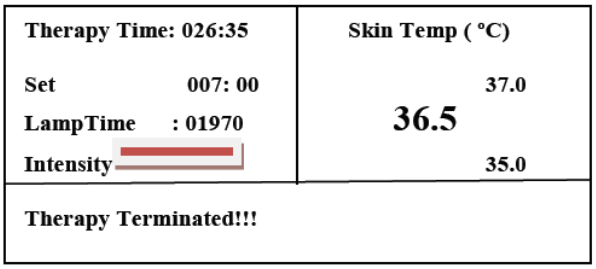
Service Screen



Alarm Screen



Therapy Terminated Screen



CHECKING READINESS FOR OPERATION

CHECKING READINESS FOR OPERATION

Check below situations before using the phototherapy unit:

WARNING

Check that an adequate voltage is supplied to the equipment.

WARNING

Verify that the brakes of casters are closed to avoid any movement of equipment during the treatment.

WARNING

Check the cooling channels and verify the channels are not obstructed.

WARNING

Verify that all LEDS are illuminated.

WARNING

Inspect the parts of equipment and ensure it has not physical damage.
Never operate the device if it has damaged parts or does not seem to operate properly.

WARNING

In order to avoid risk of eye damage, always use proper eye protector.

WARNING

The phototherapy is ready for operation only when all checks have been carried out successfully. In case of any unsuitableness contact technical service support.

.

EQUIPMENT OPERATION

Switching Equipment On 23

Preparation of Patient and Equipment 24

Adjusting Parameter ‘’Set ‘’..... 25
Adjusting Skin Temperature Alarm Limits..... 25
Starting Therapy 25

Alarms 26

Pausing Therapy 26

Terminating Therapy 26

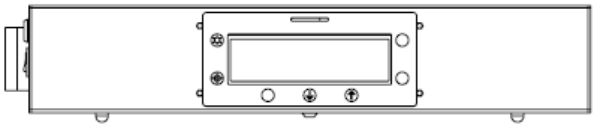
Resetting Total Lamp Usage Time 27

Switching Equipment off 28

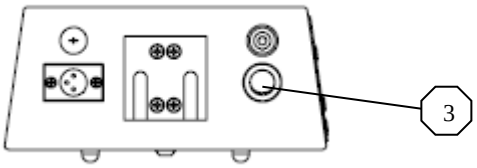
EQUIPMENT OPERATION

Switching Equipment On

Connect BILILED MAXI™ to proper line power.



Switch equipment on using the on /off (3) button placed to the side of the control panel.



Self-test is performed automatically when the equipment is on and opening screen is displayed.

NOVOS **Bililed Maxi Ver. 3.0.1**

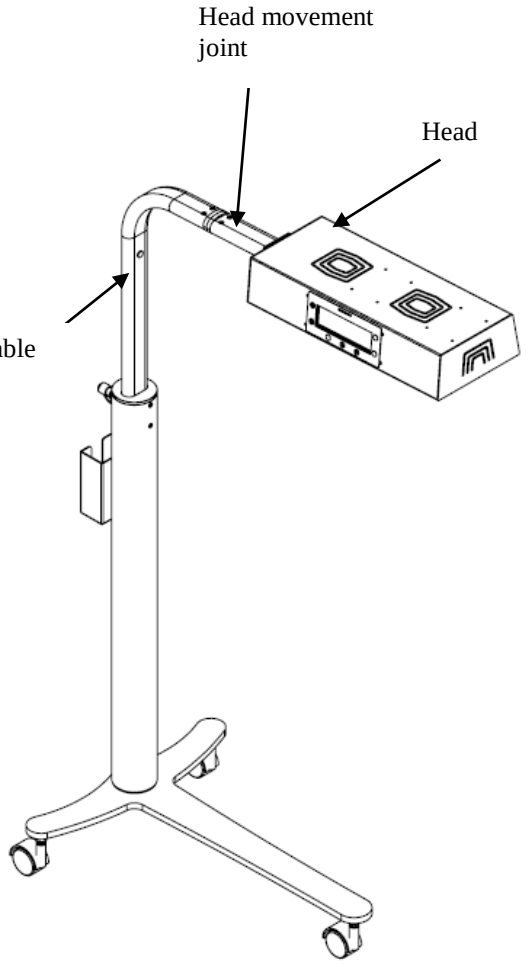
After the opening screen, main operating screen is displayed.

Therapy Time: 026:35	**Skin Temp (°C)**
Set 007: 00	**37.0**
Lamp Time : 01970	**36.5**
Intensity	**35.0**

Preparation of Patient and Equipment

BILILED MAXI should be positioned so that illuminated area mainly cover the thoracic-abdominal area of the baby.

Detached BILILED MAXI head could be used directly putting onto the incubator canopy, or BILILED MAXI with mobile stand could be used onto the incubator canopy or close to a radiant warmer positioning the illuminated area over the baby using the height adjustable column or head movement joint.



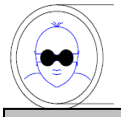
NOTE: BILILED MAXI head could be detached from the head movement joint lifting it up.

Red focus light may be helpful for positioning the equipment for the optimum adjustment of the illuminated area on the thoracic-abdominal area.

NOTE : Press the focus button for the focus light.

Brakes of casters should be closed to avoid any movement of equipment during the treatment in case of using BILILED MAXI with mobile stand.

Use eye protector for infant in order to avoid risk of eye damage.



WARNING

During the therapy eyes of baby must be protected by using eye protector.

WARNING

Before starting therapy, inspect all LEDS whether they are working properly or not. Improper LEDS working may cause decrease irradiance efficacy and therapy efficiency.

Adjusting Parameter ‘’Set ‘’

The parameter ‘’Set’’ means desired therapy time adjusted by caregiver.
Desired therapy time can be adjusted in terms of hour and minute.
Adjusting format is as hhh: mm

On the main screen when you press ‘’Set ‘’ button, field for hhh: mm starts to flashing.
Adjust hour value for therapy time by pressing ↑ or ↓ buttons. Then press ‘’Set’’ button.
The minute value field will start to flash.
Adjust minute value for therapy time by pressing ↑ or ↓ buttons. Then press ‘’Set’’ button.

The default value of ‘Set’ is 10 hours. If you would like to start therapy with default value, just press ‘’Set’’ button twice.

When you adjust parameter ‘Set’ as 000:00 and then start therapy, the equipment will operate continuously without stopping unless caregiver terminates the therapy.

Warning: When the therapy is started with set value as 000:00 , Therapy can only be terminated manually by pressing Pause and then Reset buttons. In case of selection of unlimited therapy time (000:00), we recommend to use alternative time counter to check applied therapy time. Exceeded therapy may be harmful to the patient.

Adjusting Skin Temperature Alarm Limits

On the main screen, when you press ‘set’ button twice, skin temperature upper alarm limit field starts flashing.
Adjust skin temperature upper alarm limit value by pressing ↑ or ↓ buttons. Then press ‘’Set’’ button.

Then the skin temperature lower alarm limit field will start to flash.
Adjust skin temperature lower alarm limit value by pressing ↑ or ↓ buttons. Then press ‘’Set’’ button.

After adjusting skin temperature alarm limits, you return to main screen automatically.

Starting Therapy (Start Function)

Therapy starts by pressing “ Start ” button on the main screen. Lamps illuminate and therapy time starts counting the therapy period.

Light intensity level is adjusted to level 5 automatically for each switching on the equipment. Intensity can be adjusted by care giver before starting the therapy or during the therapy at any time.

NOTE
Therapy is paused by pressing “ Pause ” button and is ended by pressing “Reset” button. Otherwise therapy will continue unless terminated.

WARNING
Information messages or warnings related with infant and/or equipment during the therapy are explained in “ Safety Systems ” section.

NOTE
NOVOS recommends using intensity at level 5.
Intensity values at different levels :

Level	Light intensity -mW/cm2 (35 cm)
5	3,7
4	2,8
3	1,9
2	1,0
1	0,5

Alarms

High/Low skin temperature alarm

Bililed Maxi warns caregiver with an audible alarm and a message on the screen if the measured skin temperature of the infant exceeds the adjusted skin temperature alarm limits.

To silence audible alarm for 15 minutes, press ‘Reset ‘ button.

After 15 minutes, if the alarm situation continues, audible alarm will be active again.

Skin Probe Fail alarm
If the skin probe is disconnected from the main unit, ‘Skin Probe Fail’ message will be seen on the screen with an audible alarm.
To silence this alarm press ‘Reset’ button. When you silence ‘Skin Prob Fail’ alarm, ‘Skin Prob Fail ‘ message can be seen on screen but the alarm sound will not be heard again otherwise you switch on and off equipment.

Pausing Therapy (Pause Function)

Therapy can be interrupted by pressing the “ Pause ” button at any time. Led lights will go off, “ Pause Screen ” will be seen and equipment will be in stand by/pause condition. Press “ Start ” button to continue therapy again.

Pause function is used for maintaining the therapy time during the feeding of the baby or for any clinical reason (MRI imaging etc) that tharapy needs to be interrupted. At the end of the interrupted period, therapy timer will start again counting the therapy time following the starting of the therapy by pressing the “ start ” button.

The conditions below during the ongoing therapy is the equivalent of pause function :

Switching the equipment off using the on/off button
During the ongoing therapy, therapy time will be maintained in case of a switch off the equipment using the on/off button. Therapy timer counts starting from the previous time value on switching the equipment on and pressing the start button

Interruption of voltage supply
During the ongoing therapy, therapy time will be maintained in case of a power supply interruption. Therapy timer counts starting from the previous time value following the power supplied to the equipment and start button depressed.

Terminating Therapy

a- When the therapy time counter reaches adjusted ‘set’ value

At the end of the adjusted therapy time, equipment terminates therapy automatically and warns caregiver with an audible alarm and a text message on screen.

b- With ‘ Reset’ Function

Press “ Reset ” button for 5 seconds to terminate the ongoing therapy. Then leds will go off and therapy time counter will be reset (000 : 00) for a new patient. Equipment may be switched off or therapy can be started again pressing the start button for a new patient.

WARNING
If therapy time counter shows the previous therapy time, before pressing the “ start “ button and starting a new therapy for a new patient, it is necessary to reset therapy timer using the reset function.

Resetting Total Lamp Usage Time

Average led module usage time is 20.000 hours. Led module should be replaced and total lamp usage time should be reset after a period of 20.000 hours usage.

Total lamp usage time counter is checked by the microprocessor automatically on each switching the equipment on. " Call Service !!! " message is shown on the screen to warn user when the lamp usage time counter is 20.000 hours. In this case it is not possible to use the device without replacing the LED module and resetting total lamp usage timer.

For resetting total lamp usage timer :

1. Switch off the equipment.

2. Switch the equipment on while pressing the focus and intensity level adjustment buttons at the same time.

3. " Lamp Timer Reset! " message is shown on the screen and device turns to main operating screen automatically.

WARNING
Contact an authorized technical service for the replacement of the LED module in case of " Call Service! " message is seen on the screen.

WARNING
Resetting total lamp usage time function is only to be used after the replacement of LED module.

Switching Equipment Off

Device is switched off when the switch position is on " 0 "

SAFETY SYSTEMS & ALARMS

Alarms and Info Messages …….. 29
Automatic LEDS Shut Off …..…… 29
Control System for Inspection of LEDS efficiency …… 29

SAFETY SYSTEMS & ALARMS

Alarms and Info Messages

Alarm & Info	Cause	Proposal
Call Service !!!	Led usage time is ended.	Contact technical service to replace the led module
Lamp Timer Reset !	Lamp usage time is reset.	-
Low Skin Temperature	Skin Temperature is below low skin temperature alarm limit.	Check Baby
Low Skin Temperature	Skin probe can be removed from baby's skin.	Re-attach skin probe to baby's skin.
High skin Temperature	Skin Temperature is above high skin temperature alarm limit.	Check Baby
Skin Probe Fail/Disconnect	Skin Probe disconnected from the equipment or skin probe is faulty.	Connect Skin Probe to the equipment or replace the skin probe with a new one.

Automatic LEDS Shut Off

Leds are automatically shut off and therapy is paused if the temperature of the LED module increases above 60 ºC because of any technical problem and/or high ambient temperature. Leds are automatically illuminated again when the temperature of led module decreases to 40 ºC.

WARNING

LED module illuminates uninterrupted under normal operation conditions. Contact a certified NOVOS technical service for a detailed control of the equipment in case of interrupted LED module operation

LEDS Efficiency Control System

For the next switch on the equipment, " Call Service ! " message is shown on the screen if the total lamp usage time is higher than 20.000 hours. Therapy cannot be started in case of " Call Service " message and equipment usage is prevented with the inefficient leds. Led module should be replaced and total lamp usage time should be reset for using the equipment again.

ROUTINE CLEANING & MAINTENANCE

Cleaning and Disinfection 32
Preventive Maintenance 33
Cleaning of Cooling Duct 33
Intensity Control 33
Replacement of Led Module 33

ROUTINE CLEANING & MAINTENANCE

Cleaning and Disinfection

BILILED MAXI™ must be thoroughly cleaned and disinfected periodically according to approved hospital protocols.

WARNING
Always disconnect power supply before cleaning and disinfection.

- Remove visible soiling with a disposable cloth and detergent.
- Wipe-disinfect the surfaces.
- After allowing disinfectant to take effect (see manufacturer's directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.

WARNING

Do not allow any moisture (disinfectant and liquid detergent) enter the unit, control panel and lens.
Do not disinfect control panel by immersion or spraying.

WARNING

Do not disinfect unit, control panel and any parts of unit by immersion.

WARNING

Led module including the lenses should be cleaned with a soft, damp cloth.

WARNING

Do not touch lens by finger. The dirt, body oil, perfume or such ingredients available on finger may damage the optical property.

WARNING

Do not use organic solvents sometimes used for cleaning and disinfecting (e.g., alcohols, phenols, halogen releasing compounds, oxygen releasing compounds, strong organic acids, etc.) Exposure to such substances may cause damage of equipment and parts.

CAUTION

We recommend using Ammonia Quaternary.

WARNING

Do not allow any moisture (disinfectant and liquid) enter the unit.

Preventive Maintenance

This equipment must be inspected and serviced at regular 1 year intervals. A record must be kept on this preventive maintenance. We recommend obtaining a service contract with NOVOS Service through your vendor.

For repairs of BILILED MAXI phototherapy we recommend that you contact NOVOS Service.

Cleaning of Cooling Duct

For effective operation of the device and long-lasting use of LED module, cooling duct must be free of dust. Blocked cooling channels because of dust may cause inside temperature increase and shut off the leds.

Intensity Control

Expected life of led module is about 20.000 hours. However it is recommended to follow up the irradiance with a radiation monitor to assure a better evaluation of the actual efficacy of the leds. Led module should be replaced when there is a loss of 25% of the irradiance.

Replacement of Led Module

We recommend replacing led module when led usage time is 20.000 hours. For replacement of led module contact NOVOS technical service or authorized local service in your region.

TROUBLESHOOTING

TROUBLESHOOTING

Fault	Cause	Proposal
The equipment does not turn on	Power cord disconnect.	Connect the power cord to adequate socket.
	Burnt fuse	Contact a certified NOVOS technical service to replace the fuse
	On/off button is on 0 position.	Position on/off button to 1
	Power adaptor failure.	Replace power adaptor with new one.
	Electrical problem with equipment.	Contact a certified NOVOS technical service.
Therapy does not start	May not be pressed Start button.	Press Start button.
	Internal electrical problem	Contact a certified NOVOS technical service
Led module/some of the leds does not light up	Electrical failure.	Do not use the equipment and contact a certified NOVOS technical service

Unable to display baby's skin temperature	Skin Probe disconnected from the equipment or skin probe is faulty.	Connect Skin Probe to the equipment or replace the skin probe with a new one.

TECHNICAL CHARACTERISTICS

Environmental Requirements 37
Irradiance Specification 37
Measures and Control Parameters 37
Electrical Specification 37
Dimensions 37
Standards and Directives 37

TECHNICAL CHARACTERISTICS

Environmental Requirements

Operating	Temperature	23 ºC to 28 ºC
	Humidity	5-99% RH, non condensing
Storage	Temperature	-20 ºC to 50 ºC
	Humidity	10-95% RH, non condensing
Noise Level	0 dBA	

Irradiation Specifications

Spectral Irradiance	420-500 nm
Light focus center	>3 mW/cm² (≈60 µW/cm²/nm)
Average lamp usage	20.000 hours

Measures and Control Parameters

Total Time	Adjustment	0-99999 hours
	Measurement accuracy	1 hour
Therapy Time	Adjustment range	0 – 99 hours
	Measurement accuracy	1 minute

Electrical Specifications

Voltage	220 V ± %10, 50 Hz, Type BF, Class 2
Fuse	3 A
SMPS	12 V – 6, 67 A

Dimensions

Width	650 mm
Dept	180 mm
Height (Min)	840 mm
Height (Max)	1520 mm
Height (Head)	85 mm

Standards and Directives

EN 60601-1
EN 60601-2-50
ISO 13485:2003
CE1984
Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ No L 169/1 of 1993-07-12)

MANUFACTURER

NOVOS TIBBİ CİHAZLAR SAN. TİC. İTH. VE İHR. LTD. ŞTİ.

Kazım Karabekir Cad. Başkent İş Merkezi No : 91/67 İskitler 06060 ANKARA TÜRKİYE

Tel : +90.312.384 15 88
Faks : +90.312.384 15 98
E.mail : info@NOVOS.com.tr
WEB : www.NOVOS.com.tr

Note : NOVOS, reserves the right to make changes without notice in design, specifications and models

BILILED MAXI® is registered trade mark of NOVOS Ltd Sti.

© NOVOS TIBBİ CİHAZLAR SAN. TİC. İTH. VE İHR. LTD. ŞTİ. (2009)